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Docket No. G-046US02PCT
Serial No. 09/762,311Remarks

Claims 42-63 were pending in the subject application. By way of the amendment of this date, claims 64-73 have been added, claim 44 has been canceled, and claims 42, 43, 46, and 48-50 have been amended. In response to a restriction requirement, claims 42-56 and 59 and the biallelic marker at position 9494 of SEQ ID NO: 1 were elected for examination on April 24, 2003. Certain of the claims have been amended for the purpose of expediting the patent application process in a manner consistent with the Patent and Trademark Office Patent Business Goals (PBG), 65 Fed. Reg. 54603 (September 8, 2000), in order to advance prosecution and facilitate the business interests of Applicant(s). Support for these Previously Presented claims and the amendments to the pending claims can be found throughout the subject specification, including, for example, the originally presented claims. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

As an initial matter, Applicants note that the Office Action mailed July 22, 2003 does not indicate that the Examiner considered Applicants' Information Disclosure Statement that was filed in this application. Accordingly, Applicants respectfully request that the Examiner make of record the Information Disclosure Statement submitted to the Patent Office on December 4, 2001 in the subject application. Should a copy of the Information Disclosure Statement be required, Applicants respectfully request that the Examiner contact the undersigned in order to complete the records of the Patent Office.

In addition, Applicants note that the Examiner has not made an acknowledgment on the Office Action Summary page of Applicants' claim for domestic priority under 35 U.S.C. § 119(c) (to a provisional application). Attached with this Amendment is a Submission of Second Supplemental Application Data Sheet Under 37 CFR 1.76 showing the Domestic Priority Information on page 4. In addition, Applicants have corrected the filing date of the International Application number PCT/IB99/01444 and amended the Assignee information. Applicants respectfully request that the domestic priority be acknowledged and made of record by the Examiner in the subject application and that an updated Filing Receipt be transmitted to the undersigned.

Claims 42-56 and 59 have been rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for isolated nucleic acids consisting of SEQ ID NOs: 1 or 2, isolated

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nucleic acids comprising SEQ ID NOs 3 or 4, and isolated nucleic acids consisting of at least 12 nucleotides of any one of SEQ ID NOs: 1-4, does not reasonably provide enablement for nucleic acids comprising SEQ ID NOs: 1 or 2, nucleic acids consisting essentially of 12 consecutive nucleotides of SEQ ID NOs: 1-4, or nucleic acids having a "G" at nucleotide position 9494 of SEQ ID NO: 1 does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Office Action contends that the claims embrace a genus of TBC-1 nucleic acids and fragments thereof that are not adequately taught in the specification and that the use of these fragments is not supported by adequate teachings in the subject application. Applicants respectfully traverse.

Applicants respectfully submit that the claimed invention is described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For example, it is respectfully submitted that the specification provides adequate written description of polynucleotides that consist essentially of (or consist) of a contiguous span of 8 to 50, 18-35, or 25 nucleotides of SEQ ID NOs: 1 or 2 and that contain a biallelic marker within four nucleotides of the center (or at the center) of said polynucleotide.

Additionally, it is respectfully submitted that the subject specification teaches a variety of flanking sequences that can be provided for the polynucleotides of SEQ ID NOs: 1 or 2 (or fragments thereof having lengths specified in the claims). For example, the specification teaches that: 1) the sequences can be inserted into a variety of vectors (see pages 57-59); or 2) that a variety of promoters, enhancers, or termination sequences can be linked to the sequences (pages 58-61). Thus, it is respectfully submitted that adequate written description of a variety of elements that can form flanking regions of the claimed polynucleotides has been provided by the subject application. Accordingly, Applicants respectfully request the withdrawal of this point of rejection in view of the foregoing arguments and the amendments made to the claims.

Claims 42-56 and 59 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action argues that the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors were in possession of the claimed invention at the time the

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application was filed. The Office Action further argues that the application fails to teach the genus of any homolog, splice variant, biallelic variant or mutant form of TBC-1 and that the application as, filed, fails to teach a representative number of species that fall within the claimed genus. While Applicants do not agree with the Examiner's position in this regard, it is respectfully submitted that the amendments made to the currently pending claims have rendered this rejection moot. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 43-56 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action argues that the recitation of "TBC-1 related biallelic marker" is unclear. Applicants respectfully submit that this issue is moot in view of the amendments made to the claims of the subject application. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 50 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Zon *et al.* (U.S. Patent No. 5,700,927). The Office Action argues that the polynucleotide of Zon *et al.* anticipates the subject invention on the basis that while the specification specifically excludes the murine TBC-1 polypeptides, the murine polynucleotides are not so excluded. Applicants respectfully submit that Zon *et al.* fail to anticipate the invention of claim 50 as the claim has been amended to provide for the specific exclusion of murine TBC-1 as the encoded polypeptide. Accordingly, withdrawal of the rejection is respectfully requested.

Applicants also respectfully submit that Zon *et al.* fail to anticipate the invention of claims 65 and 68 as the claims provide for the specific exclusion of murine polynucleotides that encode the murine TBC-1 polypeptide. Applicants note that the Office Action argues that the polynucleotide of Zon *et al.* anticipates the subject invention on the basis that while the specification specifically excludes the murine TBC-1 polypeptides, the murine polynucleotides are not so excluded.

It is respectfully submitted that the observation of a lack of literal support by the Patent Office does not, in and of itself, establish a *prima facie* case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. § 112. See *Ex parte Parks*, 30 USPQ2d 1234 (Bd. Pat. App. Int. 1993) citing to *In re Herschler*, 591 F.2d 693, 200 U.S.P.Q. 711 (CCPA 1979), *In re Edwards*, 568 F.2d 1349, 196 U.S.P.Q. 465 (CCPA 1978; and *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90

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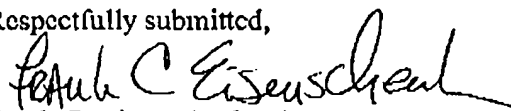
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(CCPA 1976). Applicants respectfully submit that if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed, there is no requirement for literal support for the claimed invention. *In re Anderson*, 471 F.2d 1237, 176 U.S.P.Q. 331 (CCPA 1973). In the case of the instant invention, it is respectfully submitted that the as-filed disclosure (which explicitly excluded a polypeptide that has the same amino acid sequence as the murine TBC-1 polypeptide) would have conveyed to one skilled in the art that both the murine TBC-1 polypeptide and the murine TBC-1 polynucleotide of Zon *et al.* were outside the scope of the present invention given the relationship of these two molecules (see for example SEQ ID NO: 1 of Zon *et al.* providing both the polynucleotide and polypeptide sequences of murine TBC-1). Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

In view of the foregoing remarks and the amendments to the claims, the applicants believe that the pending claims are now in condition for allowance, and such action is respectfully requested. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Submission of Second Supplemental Application Data Sheet Under 37 CFR 1.76

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